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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SEPEHR FARIABI

Appeal 2010-001837
Application 10/750,079
Technology Center 3700

Before KEN B. BARRETT, PHILLIP J. KAUFFMAN and MICHAEL L.
HOELTER, *Administrative Patent Judges*.

HOELTER, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Sepehr Fariabi (Appellant) seeks our review under 35 U.S.C. § 134 of the final rejection of claims 37-85. Claims 1-36 have been canceled. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

THE INVENTION

This invention pertains to an arterial stent.

Claim 37, reproduced below, is representative of the subject matter on appeal.

37. A cylindrically shaped balloon expandable stent configured for use in a coronary artery, comprising:

a plurality of independently expandable and interconnected cylindrical elements formed of an alloy containing cobalt, chromium, molybdenum, and nickel, and one alloy component selected from the group consisting of tungsten, iron and manganese, and generally aligned along a common longitudinal axis; and

the stent has a first low profile configuration for delivery and a second radially expanded configuration and is plastically deformable from the first low profile delivery configuration to the second radially expanded configuration, the second radially expanded configuration having a diameter suitable to hold open the coronary artery;

wherein the cylindrical elements of the stent assume the first low profile delivery configuration through compression and have an elasticity insufficient to allow expansion from the first low profile delivery configuration to the second radially expanded configuration without plastic deformation.

REFERENCES

The prior art relied upon by the Examiner is:

Bokros	U.S. 4,300,244	Nov. 17, 1981
Hillstead	U.S. 4,856,516	Aug. 15, 1989
Tower	U.S. 5,217,483	Jun. 8, 1993
Mayer	U.S. 5,824,077	Oct. 20, 1998
Robinson	U.S. 5,891,193	Apr. 6, 1999

THE REJECTIONS

The following Examiner's rejections are before us for review:

1. Claims 37-50, 53, 54, 56-76, and 82-85 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Robinson and Mayer (Ans. 3).
2. Claims 51 and 52 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Robinson and Mayer as applied against claim 37 and further in view of Hillstead or Tower (Ans. 7).
3. Claims 55 and 77-81 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Robinson and Mayer as applied against claim 37, and further in view of Bokros (Ans. 7).

OPINION

Appellant argues that each claim on appeal calls for a “balloon-expandable” stent that undergoes “plastic deformation” in order to attain its expanded state within an artery (App. Br. 12). Appellant contends that the “independent claims do not lay claim to the process by which such property is imparted but claim the structural characteristics that are inherent in the resulting stent” (App. Br. 12).

A. *The Rejection of Claims 37-50, 53, 54, 56-76 and 82-85 as being Unpatentable over Robinson and Mayer*

Appellant addresses each independent claim but offers substantially the same argument for each. Appellant does not offer separate arguments for the dependent claims. We deem Appellant to argue claims 37-50, 53, 54, 56-76 and 82-85 as a single group (App. Br. 12). We select independent claim 37 as representative of this group with the remaining claims standing or falling with claim 37. *See* 37 C.F.R. § 41.37(c)(1)(vii). Appellant's contentions are addressed below.

1. *Robinson Does Not Suggest Expansion by Plastic Deformation Within the Vessel For Which it is Configured for Use.*

When addressing Robinson, Appellant states that

[w]hile it is true that the wire [of Robinson] is plastically deformable and the resulting structure is ultimately plastically deformable, there is no suggestion or teaching that the structure formed of the bent wire is capable of attaining its expanded configuration *within the vessel for which it is configured for use* (as is claimed) by plastic deformation

(App. Br. 13) (italics added). More specifically, Appellant contends that for Robinson's stent to undergo plastic deformation, it "would have had to have been expanded well beyond the diameter of the coronary artery" and that Appellant's device and Robinson's device result "in two mutually exclusive intended uses" (Reply Br. 3-5).

As there is no dispute that Robinson's wire can be bent (*See* Robinson 5:31-51, 6:35-37), the Examiner finds that Appellant's assertion "is based upon where the device is intended to be utilized and not on any particular

structure” (Ans. 8). The Examiner states that Robinson’s stent “could be expanded to a state where there would be no bends in the wires” and that this “expanded diameter reads on the ‘diameter suitable to hold open the coronary artery’ as claimed” (Ans. 9).

Rowe v. Dror, 112 F.3d 473, 478 (Fed. Cir. 1997) states that “where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation.” The preamble to Appellant’s claim 37 states that the claimed stent is “for use in a coronary artery.” The body of claim 37 further recites a diameter “suitable to hold open the coronary artery.” We conclude that this claim language addresses the intended use of Appellant’s stent and is not a claim limitation. We agree with the Examiner’s finding that Appellant’s assertions are based on where the device is intended to be used and not on any claimed structure. Further, Appellant does not provide any evidence that Robinson’s stent is incapable of undergoing plastic deformation when expanded or that Robinson’s stent is incapable of the use claimed. Accordingly, we are not persuaded by Appellant’s contention.

2. *Robinson’s Stent is Self-Expanding and Cannot be Plastically Deformed to its Expanded State, i.e., the State it is Already In*

Claim 37 states “wherein the cylindrical elements of the stent ... have an elasticity insufficient to allow expansion from the first low profile delivery configuration to the second radially expanded configuration without plastic deformation.” (Emphasis added). Appellant contends that unlike this claim language, Robinson “has an elasticity that is sufficient to allow its

expansion to the expanded configuration” and that Robinson “cannot be plastically deformed to its expanded state, i.e., the state it is already in” (App. Br. 13). The Examiner addresses this contention by more specifically identifying “what the Examiner considers the expanded configuration” to be which is “a configuration of the bends (37) of [Robinson’s] Figure 4 being completely unbent” (Ans. 9). Appellant acknowledges as “true that [Robinson’s] wire is plastically deformable” when expanded to an unbent state (App. Br. 13). Accordingly, we are not persuaded by Appellant’s contention.

3. *Robinson’s Stent Does Not have the Unexpected Ductility Necessary for it to Undergo Plastic Deformation*

Appellant contends that Robinson’s material is inherently elastic which is why it is “for use in self-expanding applications” (App. Br. 15). Appellant does not dispute that his material and Robinson’s material “is extremely similar” or “closely related,” but Appellant explains that “[w]ithout the proper treatment of the alloy prior to its use as is described in the patent application,” Robinson’s material “simply doesn’t have the ductility that is necessary for it to undergo plastic deformation” (App. Br. 15). Appellant asserts that because of this additional processing, its material “has different physical properties that unexpectedly renders a stent” that is “compatible with balloon delivery systems” (App. Br. 15, *see also* Reply Br. 5-6).

Appellant acknowledges that “the process by which such product is made is not the focus of the present patent application” even though it yields “a different structure than what is described in the cited references” (App.

Br. 15). The Examiner, however, maintains that the burden has shifted “to Appellant to show an unobvious difference between the claimed invention and the closest prior art” and that “Appellant failed to provide such evidence” (Ans. 9-10).

“On appeal to the Board, an applicant can overcome a rejection by showing insufficient evidence of *prima facie* obviousness or by rebutting the *prima facie* case with evidence of secondary indicia of non[-]obviousness.” *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998); *see also In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990) (“when the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.”). Here, the burden has been shifted to Appellant to show that the claimed alloys have plastic deformation properties distinct and unobvious from those of Robinson. Appellant has submitted no evidence (Evidence Appendix: “None”) regarding these plastic deformation properties other than referring to the Specification for a description of the manufacturing processes involved (*See* Reply Br. 5-6). Based on the record before us, we are not persuaded by Appellant’s contention.

4. *Robinson Teaches Away from Appellant’s Invention*

Appellant contends that Robinson “teaches away” from being sized to expand as set forth by the Examiner because to expand Robinson “by plastic deformation would require its expansion to a diameter well beyond the diameter of such artery and would therefore render it unsuitable for ‘use in a coronary artery’ as is required by all claims” (App. Br. 15-16, *see also* Reply Br. 3-4). We are not persuaded by this contention as it again addresses

intended use. Further, Appellant's claim 37 does not express a specific upper limit on expanded size and we agree with the Examiner's finding that "if a stent designed for a child were used in an adult, it could be expanded to have no bends" (Ans. 10). Additionally, Appellant's contention that Robinson teaches away is unsupported by any showing how Robinson criticizes, discredits, or discourages the claimed invention. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004).

5. *The Claiming of a Characteristic Comprises a Structural Limitation*

Appellant contends that while "requiring the stent to actually undergo the plastic deformation would comprise the claiming of a use, the claiming of a characteristic comprises a structural limitation" (Reply Br. 3). More specifically, Appellant contends that "such structural limitation is what effectively avoids the cited art" because a "stent that is plastically deformable as claimed avoids the prior art even if it is never deformed, i.e., used" (Reply. Br. 3). Presuming, *arguendo*, Appellant's statements are correct, Appellant nevertheless acknowledges that at least Robinson's stent is plastically deformable (*See* App. Br. 13). Consequently, Appellant's contention that this claimed structural limitation (i.e., "plastically deformable") avoids the cited art is not persuasive.

6. *The Non-Obviousness of a Structure can be Supported by How it is Used or How it is Usable*

Appellant contends that "while the claims require a distinguishing structure (as claimed) the non-obviousness of such structure can clearly be

supported by how it is used or how it is usable” (Reply Br. 3). Appellant provides no evidence or citation to support this contention (Reply Br. 3). To the contrary, it has long been settled that claims must be distinguished from the prior art in terms of structure rather than function. *See In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir.1997) (claims for conical dispensing top for popped popcorn unpatentable over prior art disclosing conical spout for open-ended containers, which contains all structural limitations recited in the claims). As Appellant bases this contention on the use, and not the structure, of its claimed device, we are not persuaded.

Based on the above, we affirm the rejection of claim 37, as well as claims 38-50, 53, 54, 56-76, and 82-85, as being unpatentable over Robinson and Mayer.

B. The Rejection of Claims 51 and 52 as being Unpatentable over Robinson and Mayer as Applied Against Claim 37 and Further in view of Hillstead or Tower

Appellant argues claims 51 and 52 as a single group (App. Br. 16). We select independent claim 52 as representative of this group with the remaining claim standing or falling with claim 52. *See* 37 C.F.R. § 41.37(c)(1)(vii).

Appellant contends that “the cited art teaches away” as the elasticity required for self-expanding applications “is irreconcilable with the ductility required for balloon-expandable applications” (App. Br. 16). The issues regarding ductility (i.e., plastic deformation) have previously been discussed, are incorporated herein and will not be repeated. As regarding “balloon-expandable,” the preamble to claim 52 recites a “balloon-

expandable” stent. This phrase is not used elsewhere in the claim. We are instructed that “where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation.” *Rowe*, 112 F.3d at 478. We find that Appellant has defined a structurally complete invention in the claim body and as such, the preamble’s inclusion of “balloon-expandable” is not a claim limitation. Further, Appellant has not presented evidence that the cited art, and particularly Robinson, is incapable of being “balloon-expandable” nor does Appellant show where the cited art criticizes, discredits, or discourages the claimed invention (*See Fulton*, 391 F.3d at 1201). Accordingly, we are not persuaded by Appellant’s contention.

Claim 52 recites “an interior chamber *configured to receive* an expandable member for plastically expanding the stent” (italics added). The Examiner concludes that the plastic deformation characteristic “is not positively required for claim 52” (Ans. 8). Appellant contends that this claimed configuration “clearly requires” the stent to undergo plastic deformation and that “it is positively required for the material to be plastically deformable” (Reply Br. 2).

Appellant’s claim is directed to an apparatus claim and thus the apparatus must be distinguished from the prior art in terms of structure, rather than function. *See Schreiber*, 128 F.3d at 1477. As Appellant has not shown that the cited art is incapable of undergoing plastic deformation (in fact, Appellant acknowledges that at least Robinson is capable of plastic deformation, *see App. Br. 13*), we are not persuaded by Appellant’s contentions.

Based on the above, we affirm the rejection of claim 52, as well as claim 51, as being unpatentable over Robinson and Mayer as applied against claim 37 and further in view of Hillstead or Tower.

C. The Rejection of Claims 55 and 77-81 as being Unpatentable over Robinson and Mayer as Applied Against Claim 37 and Further in view of Bokros

Appellant argues claims 55 and 77-81 as a single group (App. Br. 16). We select independent claim 77 as representative of this group with the remaining claim standing or falling with claim 77. *See* 37 C.F.R. § 41.37(c)(1)(vii).

Again, Appellant contends that “the cited art teaches away” from the present invention because the elasticity required for self-expanding applications “is irreconcilable with the ductility required for balloon-expandable applications” (App. Br. 16). The issues regarding ductility (i.e., plastic deformation) and “balloon-expandable” have previously been discussed, are incorporated herein and will not be repeated. As all the contentions presented have previously been addressed, we affirm the rejection of claim 77, as well as claims 55 and 78-81 over Robinson and Mayer as applied against claim 37 and further in view of Bokros.

DECISION

The decision of the Examiner to reject

1. claims 37-50, 53, 54, 56-76 and 82-85 under 35 U.S.C. § 103(a) as being unpatentable over Robinson and Mayer is affirmed.

2. claims 51 and 52 under 35 U.S.C. § 103(a) as being unpatentable over Robinson and Mayer as applied against claim 37 and further in view of Hillstead or Tower is affirmed, and

3. claims 55 and 77-81 under 35 U.S.C. § 103(a) as being unpatentable over Robinson and Mayer as applied against claim 37 and further in view of Bokros is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED

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